

In re Application of:  
Germino et al.  
Application No.: 09/904,968  
Filed: July 13, 2001  
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PATENT  
Atty Docket No.: JHU1680-2

## REMARKS

Claims 1, 20, 25, 44, 59 and 60 have been amended. Claims 6, 8-11, 26-27, 45, 53-54, 72-75 have been canceled without prejudice or disclaimer. Claims 76-78 have been added. Claims 18, 30 and 58 were previously withdrawn. Claims 5, 12-15, 38, 43, 62-71 were previously canceled.

Subsequent to the entry of the present amendment, claims 1-4, 6-11, 16-37, 39-61 and 76-78 are pending and at issue. These amendments and additions add no new matter as the claim language is fully supported by the specification and original claims.

The Office Action states that only claims 72-75 have been examined on their merits because either Applicants have not specified the 8 elected primers as per the original election of October 24, 2003, or because the claims are directed to unelected invention(s).

Applicants submit that the amended claims are directed to the elected invention (October 24, 2003).

### I. Amendment to the Claims

Claims 1, 25, 44 and 60 have been amended to include two more sets of primers, or 4 primers. The primers are supported in the specification and in the original claims (e.g., see original claims 26-27, 45 and 54). Amendments to the claims also recite that the claimed methods require at least two steps. This is supported in the specification, e.g., Example 1 beginning at paragraph [0228] of Published Application 20030008288.

Claim 20 has also been amended to reflect that which was elected on October 24, 2003.

Claim 59 has been amended to improve its form.

Claims 76-78 have been added and are supported in the specification, for example, paragraphs [0222] and [0228] of Example 1 of the Published Application 20030008288.

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## II. Restriction/Election

According to the Office Action, Applicants need to include 8 primers as a set for further prosecution, as well as cancel unelected subject matter in claim 20.

Without conceding to the correctness of the restriction requirement, Applicants have included SEQ ID NOS: 5 and 6 and 21 and 22 to claims 1, 25, 44 and 60; and canceled unelected subject matter in claim 20.

## II. Rejections under 35 U.S.C. § 103

Claims 72 and 74 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over Klinger et al. (U.S. Patent No. 5,654,170; hereinafter “Klinger”) in view of Buck et al. (1999; hereinafter “Buck”). Claims 72 and 74 have been canceled in favor of the amended claims, thus the rejection with regards to these claims is moot. Applicants respectfully traverse this rejection as it applies to the amended [pending] claims.

According to the Office Action, *In re Duel* (USPQ 2d 1210 (Fed Cir. 1995)) allegedly provides the basis of rejection, by providing that “...a *prima facie* case of obviousness is based on structural similarity...”; and since the claimed primers represent structural homologs derived from sequences suggested by the prior art [Klinger], the claimed primers and probes are *prima facie* obvious over the cited references in the absence of secondary considerations (page 10 of the Office Action). The rejection is made with respect to claims 72 and 74, however, based on past similar rejections, Applicants presume that the rejection applies to the pending claims, and such is discussed below.

Claims 1, 25, 44 and 60 have been amended to recite the set of 8 primers as well as to recite at least a first and a second step using a subset of the 8 primers. The claimed invention is distinguished from Klinger because Klinger does not describe two amplification steps to generate a mutant form of the PKD1 gene. Example 1 of Klinger discloses whole blood samples were collected and processed (col.12, lines 63-67); the genomic DNA extracted (col.13, lines 3-4); and

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0.2-1 µg of genomic DNA was added to a PCR mixture containing 5' and 3' PKD1 primers (col.13-14). Klinger discloses that to detect PKD1 mutations, the PCR amplification product above is blotted onto a nylon membrane and probed with oligonucleotides that detect PKD1 mutations (col.13, lines 12-39). Thus, Klinger does not detect mutant forms of PKD1 as in the claimed invention.

Also, according to the Office Action, Buck allegedly supports the holding of *In re Duel*, because Buck provides direct evidence of the “equivalence” of the claimed primers and their function (page 10-11 of the Office Action). However, the combination of Klinger and Buck neither teaches nor suggests the claimed invention. Therefore, it cannot be said that Klinger alone, or combined with Buck, renders the claimed invention obvious.

Accordingly, withdrawal of rejection of claims under 35 U.S.C. §103, is respectfully requested.

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**Conclusion**

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

No fee is deemed necessary with the filing of this paper. However if any fees are due, the Commissioner is hereby authorized to charge any fees, or make any credits, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number. A copy of the Transmittal Sheet is enclosed.

Respectfully submitted,



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Lisa A. Haile  
Lisa A. Haile, J.D., Ph.D.  
Registration No. 38,347  
Telephone: (858) 677-1456  
Facsimile: (858) 677-1465

DLA PIPER RUDNICK GRAY CARY US LLP  
4365 Executive Drive, Suite 1100  
San Diego, California 92121-2133  
**USPTO Customer No. 28213**